

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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| <p>To:</p> <p>DALEY, Sean, P. Fish and Richardson P.C. 225 Franklin Street Boston, MA 02110-2804 ETATS-UNIS D'AMERIQUE</p> | <h3 style="margin: 0;">RECEIVED</h3> <p style="margin: 5px 0;">JAN 18 2005</p> <p style="margin: 0;">FISH & RICHARDSON, P.C. BOSTON OFFICE</p> |
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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(PCT Rule 71.1)

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| Date of mailing (day/month/year) 14.01.2005 | |
| Applicant's or agent's file reference 14074-014WO1 | IMPORTANT NOTIFICATION |
| International application No. PCTUS2004/004991 | International filing date (day/month/year) 20.02.2004 |
| Priority date (day/month/year) 21.02.2003 | |
| Applicant METABOLIX INC. | |

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 eprnu d Fax: +49 89 2399 - 4465 | Authorized Officer Tantum, P Tel. +49 89 2399-8143 |
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 14074-014WO1 | FOR FURTHER ACTION See Form PCT/PEA/416 | |
| International application No. PCT/US2004/004991 | International filing date (day/month/year) 20.02.2004 | Priority date (day/month/year) 21.02.2003 |
| International Patent Classification (IPC) or national classification and IPC C09J167/04, C08L67/04 | | |
| Applicant METABOLIX INC. | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | |
| Date of submission of the demand 20.09.2004 | Date of completion of this report 14.01.2005 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80238 Munich Tel.: +49 89 2399 - 0 Tx: 523656 epnu d Fax: +49 89 2399 - 4465 | Authorized Officer Masson, P Telephone No. +49 89 2399-2051  | |

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2004/004991

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-44 as originally filed

Claims, Numbers

1-83 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2004/004991

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------------|
| Novelty (N) | Yes: Claims | 50,51,83 |
| | No: Claims | 1-49,52-82 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-83 |
| Industrial applicability (IA) | Yes: Claims | 1-83 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Cf V:

Reference is made to the following documents:

- D1: IANNACE S ET AL: "POLY(3-HYDROXYBUTYRATE)-CO-(3-HYDROXYVALE RATE)/POLY-L-LACTIDE BLENDS: THERMAL AND MECHANICAL PROPERTIES" JOURNAL OF APPLIED POLYMER SCIENCE, JOHN WILEY AND SONS INC. NEW YORK, US, vol. 54, no. 10, 5 December 1994 (1994-12-05), pages 1525-1535, XP000514124 ISSN: 0021-8995
- D2: US-A-5 191 037 (DOI YOSHIHARU ET AL) 2 March 1993 (1993-03-02)
- D3: MIGUEL O ET AL: "Blends of bacterial poly(3-hydroxybutyrate) with synthetic poly(3-hydroxybutyrate) and poly(epichlorohydrin): transport properties of carbon dioxide and water vapour" POLYMER, ELSEVIER SCIENCE PUBLISHERS B.V, GB, vol. 42, no. 3, February 2001 (2001-02), pages 953-962, XP004218064 ISSN: 0032-3861
- D4: MALLARDE D ET AL: "Hydrolytic degradability of poly(3-hydroxyoctanoate) and of a poly(3-hydroxyoctanoate)/poly(R,S-lactic acid) blend" POLYMER, ELSEVIER SCIENCE PUBLISHERS B.V, GB, vol. 39, no. 15, 1 July 1998 (1998-07-01), pages 3387-3392, XP004122248 ISSN: 0032-3861
- D5: TSUJI H ET AL: "BLENDS OF CRYSTALLINE AND AMORPHOUS POLY(LACTIDE). III. HYDROLYSIS OF SOLUTION-CAST BLEND FILMS" JOURNAL OF APPLIED POLYMER SCIENCE, JOHN WILEY AND SONS INC. NEW YORK, US, vol. 64, no. 7, 14 February 1997 (1997-02-14), pages 855-863, XP000722889 ISSN: 0021-8995
- D6: HIDEKI ABE ET AL: "SYNTHESIS AND CHARACTERIZATION OF POLYU(R,S)-3-HYDROXYBUTYRATE-B-L-HY DROXYHEXANOATE AS A COMPATIBILIZER FOR A BIODEGRADABLE BLEND OF POLYU(R)-3-HYDROXYBUTYRATE AND POLY(6-HYDROXYHEXANOATE)" MACROMOLECULES, AMERICAN CHEMICAL SOCIETY. EASTON, US, vol. 27, no. 21, 10 October 1994 (1994-10-10), pages 6012-6017, XP000474772 ISSN: 0024-9297
- D7: EP-A-0 826 803 (TAKASAGO PERFUMERY CO LTD) 4 March 1998 (1998-03-04)
- D8: SCANDOLA M ET AL: "POLYMER BLENDS OF NATURAL POLY(3-HYDROXYBUTYRATE-CO-3-HYDROXYVALERAT E) AND A SYNTHETIC ATACTIC POLY(3-HYDROXYBUTYRATE). CHARACTERIZATION AND

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/US2004/004991

BIODEGRADATION STUDIES* MACROMOLECULES, AMERICAN
CHEMICAL SOCIETY. EASTON, US, vol. 30, no. 9, 5 May 1997 (1997-05-
05), pages 2568-2574, XP000688331 ISSN: 0024-9297

- D9: US-A-5 693 389 (LIGGAT JOHN JAMIESON) 2 December 1997 (1997-12-02)
- D10: WO 02/077080 A (PROCTER & GAMBLE) 3 October 2002 (2002-10-03)
- D11: WO 02/085983 A (DU PONT ; FUGULY GARRET D (US)) 31 October 2002 (2002-10-31)
- D12: EP-A-0 890 614 (GUNZE KK) 13 January 1999 (1999-01-13)
- D13: EP-A-0 450 777 (AGENCY IND SCIENCE TECHN) 9 October 1991 (1991-10-09)
- D14: WO 02/50156 A (MELIK DAVID HARRY ; SATKOWSKI MICHAEL MATTHEW (US); AUTRAN JEAN-PHILIP) 27 June 2002 (2002-06-27)
- D15: US 2002/143116 A1 (MELIK DAVID HARRY ET AL) 3 October 2002 (2002-10-03)
- D16: WO 02/059201 A (PONTI ROBERTO ; BASTIOLI CATIA (IT); GUANELLA ITALO (IT); NOVAMONT SPA) 1 August 2002 (2002-08-01)
- D17: US-B-6 221 3161 (SCHECKLIES ELVIRA ET AL) 24 April 2001 (2001-04-24)
- D18: WO 96/08535 A (PROCTER & GAMBLE) 21 March 1996 (1996-03-21)
- D19: US-B-6 191 2031 (PIERRE JEAN R ET AL) 20 February 2001 (2001-02-20)
- D20: US-B-6 228 9541 (MUTH ROSS R ET AL) 8 May 2001 (2001-05-08)
- D21: DE 43 00 420 A (BASF AG) 14 July 1994 (1994-07-14)
- D22: US-A-5 646 217 (HAMMOND TIMOTHY) 8 July 1997 (1997-07-08)
- D23: WO 95/10577 A (FULLER H B LICENSING FINANC) 20 April 1995 (1995-04-20)
- D24: WO 02/28969 A (AUTRAN JEAN PHILIPPE MARIE ; PROCTER & GAMBLE (US)) 11 April 2002 (2002-04-11)
- D25: EP-A-1 193 294 (TOHCELLO CO LTD) 3 April 2002 (2002-04-03)

Article 33(2) PCT:

Claim 1 discloses a blend of PHAs.

Document D1 discloses the same combination of technical features as disclosed in **claim 1** (pages 1525-1535).

The same remark applies also to **documents D2** (column 1; lines 24 to 26, column 2; lines 3 to 20, claims and examples), **D3** (pages 953-962), **D4** (pages 3387-3392), **D5** (pages 855-863), **D6** (tables and related text), **D7** (page 2; line 51 to page 3; line 26, claims and examples), **D8** (page 2568; right column to page 2569; left column, table 1), **D9** (column 1; lines 6 to 27, column 1; line 38 to column 2; line 55; claims and examples), **D10** (claims examples 1-2), **D11** (page 3; line 7 to page 5; line 19, page 7; lines 10 to 22, claims and examples), **D12** (page 3; lines 3 to 22, claims and examples), **D13** (column 1; lines 31 to 55, column 4; lines 20 to 28, claims, examples 1,2, column 1, lines 21 to 26), **D14** (page 3; lines 6 to 9, lines 20 to 22, page 9; lines 2 to 11, line 26, page 14; lines 25 to 27, claims, examples), **D15** (§ 10, 46, claims, examples), **D16** (pages 3-4, page 6; § 4, claims), **D17** (claims, examples, column 2; lines 16 to 51) and **D18** (page 43; line 25 to page 44; line 29).

Thus, the subject matter of **claim 1** does not meet the requirements of Article 33(2) PCT.

The same considerations apply to the subject matter of **claims 59, 64 and 80** as well as to the subject matter of dependent **claims 2 to 49, 52 to 58, 82, 60 to 63, and 65 to 79** which contain merely conventional embodiments of respectively **claims 1, 59 and 64**.

Claim 81:

Claim 81 discloses an adhesive blend composition.

Document D23 discloses the same combination of technical features as disclosed in **claim 1** (page 2, line 32 to page 3; line 10, tables 1 to 3).

The same remark applies also to **document D25** (§ 7-13, page 4, lines 19 to 21).

Thus, the subject matter of **claim 81** does not meet the requirements of Article 33(2) PCT.

Claim 83:

None of the documents discloses the same combination of features as disclosed in **claim 83**.

Thus, the subject matter of **claim 83** meets the requirements of Article 33(2) PCT.

The same remark applies also to **claims 50 and 51**.

Article 33(3) PCT:

Claims 1 to 49, 52 to 82:

The subject matter of **claims 1 to 49, 52 to 82** does not meet the requirements of Article 33(3) PCT.

Claims 83, 50 and 51:

Document D14 is considered as representing the closest prior art. The difference between **D14** and **claim 83**, is that, in **D14**, the copolymer contains only two comonomers instead of three. Since there are no examples in accordance with **claim 83**, only examples with copolymers containing only two comonomers being disclosed, there is no technical effect related to such difference.

Thus, such difference cannot represent any inventive step.

Therefore, the subject matter of **claims 83, 50 and 51** does not meet the requirements of Article 33(3) PCT.

Article 33(4) PCT:

The subject matter of **all claims** is capable of industrial applicability.

Cf VIII:

Claims 1, 59, 64, 81 and 83 are not clear since the characterization of the blend by its mechanical properties is not clear. The conditions for measuring such properties are not indicated in the claims and furthermore represent merely the technical goal to be achieved. Furthermore, there is no type of difference indicated between the two PHAs. Thus, only, the chemical composition, the molecular weight and the crystallinity could make a difference between the two PHAs and will be taken into account. Regarding the Hansen parameter and the thermal properties, such differences are rather based on the chemical composition. It is also to be pointed out that the PHAs disclosed in the examples are different due to different chemical compositions.